

Certification of Substances Division

Title:	Changes to Submitted Documentation No Longer Accepted During the Assessment Phase
Reference Document:	PA/PH/CEP (10) 85 (EN)

As part of our ongoing efforts to shorten the processing time for applications for Certificates of Suitability (CEP) and to ensure adherence to deadlines published it has been decided that changes or additions to submitted documentation under assessment which are not a consequence of a request for additional information will no longer be accepted. Following the implementation of the two-round policy in September 2008 it has been noted that changes to the initially submitted documentation represent a significant part of the evaluation process for additional information. Changes submitted during this phase present a risk that they will not be explicit, or fully documented, which may then lead to further deficiencies and ultimately the application's rejection. Or, at minimum, delays in issuing the CEP.

Changes which are not a consequence of a request for additional information must be declared as a variation immediately after the CEP has been issued. Exceptions to this new policy include administrative notifications such as company name changes and additional information following the introduction of a revised monograph.